

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 August 2001 (30.08.2001)

PCT

(10) International Publication Number
WO 01/62163 A1

(51) International Patent Classification⁷: A61B 17/115,
17/11, 17/072

(21) International Application Number: PCT/US01/05435

(22) International Filing Date: 21 February 2001 (21.02.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/510,923 22 February 2000 (22.02.2000) US

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(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,
DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,
HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,
LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ,
NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,
TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

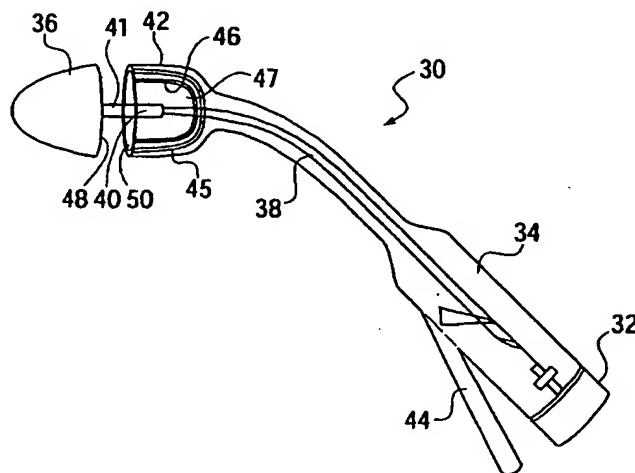
(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: A CARRIAGE ASSEMBLY FOR CONTROLLING A STEERING WIRE STEERING MECHANISM WITHIN A
FLEXIBLE SHAFT



(57) Abstract: A carriage assembly for controlling a steering wire steering mechanism within a flexible shaft, for use in gastroin-
testinal tract surgery, comprises a plurality of selectably engageable motors, including two drive motors for selectably rotating drive
shafts of a surgical attachment, two steering motors mechanically communicating with corresponding pulleys around which are
coiled directional steering wires communicating with a flexible shaft to enable the selective direction of the flexible shaft within a
spatial plane, wherein within the assembly housing the steering motors travel on a steering motor carriage and the pulleys travel on a
pulley carriage which is biased by a spring means away from the interior wall of the housing, which biases the steering wires toward
a taut state. The bias can be overcome by a carriage motor mechanically communicating with the pulley carriage to cause the flexible
shaft to go limp. Also disclosed are a series of surgical attachments which may be coupled to and utilized in conjunction with the
carriage assembly.

WO 01/62163 A1

**A CARRIAGE ASSEMBLY FOR CONTROLLING
A STEERING WIRE STEERING MECHANISM WITHIN A FLEXIBLE SHAFT**

Background of the Invention

5 Cross-Reference to Related Application

 This application is a continuation-in-part of co-pending application U.S.S.N. 09/324,452, entitled "An Electromechanical Driver Device for use with Anastomosing, Stapling, and Resecting Instruments" (attorney docket no. P-101).

Field of the Invention

10 The present invention relates generally to electromechanical devices for use with surgical instruments and more specifically to a carriage assembly for controlling a steering wire steering mechanism within a flexible shaft, suitable for use with an electromechanical driver assembly by which surgical attachments incorporating anastomosing, stapling, and resecting tools may be remotely actuated.

15 Description of the Prior Art

 Upon identification of cancerous or other anomalous tissue in the gastrointestinal tract, surgical intervention is often prescribed. The field of cancer surgery; and more specifically, the surgical procedure by which a section of the gastrointestinal tract which includes cancerous or anomalous tissue is resected, includes a number of uniquely
20 designed instruments. In combination with a description of the present instrumentation and their functions, a description of the state of the art in this surgical procedure shall also be provided.

 The first question which must be answered when determining how to treat gastrointestinal cancer relates to the specific location of the cancerous tissue. This is very
25 important insofar as the instruments which are provided in the present art have limitations relating to how far they may be inserted into the gastrointestinal tract. If the cancerous tissue is too far up the colon, for example, then the standard instrumentation provided is unusable, thus requiring special accommodations. These accommodations generally increase the risk of contamination of the surrounding tissues with bowel
30 contents, increase the length of the surgery and the corresponding need for anesthesia, and eliminate the benefits of precise anastomosing and stapling which comes from utilizing a mechanized device.

More specifically, in the event that the cancerous tissue is located at a position in the colon which is accessible by the present instrumentation, the patient's abdomen is initially opened to expose the bowel. The surgeon then utilizes a linear cutter and stapling device which cuts the tube of the colon on either side of the cancerous tissue, thereby creating two stapled ends of the bowel (a distal end which is directed toward the anus, and the proximal end which is closest to the small intestine). This is done in order to temporarily minimize contamination.

More particularly, referring to Figure 1, the bowel is placed between the scissoring elements 12, 14 at the tip of the linear stapling instrument 10. By squeezing the trigger 16 in the handle 18 of the device, the surgeon causes the scissoring elements 12, 14 to come together. A second trigger (or a secondary action of the same trigger) is then actuated to drive a series of staples 20 through the clamped end of the colon, thereby closing and transecting the ends.

The surgeon then partially opens the proximal end and inserts the removable anvil portion of an anastomosing and stapling instrument into the exposed proximal end. This step, as well as those of the remainder of the surgical procedure, are related to the functioning of this surgical instrument. More particularly, and with respect to Figure 2, the surgeon begins by taking the instrument 30 and manually turning the dial 32 at the base of the handle 34 which causes the anvil head 36 at the opposite end to advance forward. The surgeon continues to turn the dial 32 until the anvil head 36 advances to its most extreme extended position. This manual turning requires nearly thirty full rotations. Once fully extended, the anvil head of the instrument is decoupled therefrom and is inserted into the partial opening of the proximal end such that the coupling post extends outwardly therethrough. This partial opening of the proximal end is then sutured closed. The extending shaft 38 of the anastomosing and stapling instrument 30 is then inserted and advanced into the lower colon, transanally, until the coupling stem 40 thereof extends through the stapled distal end. The surgeon then joins the coupling ends of the anvil and shaft together and begins to manually rotate the dial in the handle again, this time bringing the anvil head closer to the end 42 of the shaft.

Once the anvil head and shaft are brought close together, after the surgeon has manually rotated the dial another thirty times, a grip-style trigger 44 in the handle is manually actuated. This actuation causes a circular blade 46 to advance axially out from

the tip of the shaft, and into contact with the opposing face 48 of the anvil 36. The blade cuts through the stapled-closed ends of the proximal and distal ends of the colon, thereby also cutting a new pair of ends of the proximal and distal portions of the colon. The tissue which has been severed is held in an interior volume at the end of the shaft.

5 In lock step with the cutting, the freshly opened ends are joined together by a series of staples 50 which are advanced through holes in the perimeter of the tip of the shaft (being pressed against and closed by the opposing face of the anvil). The coupled shaft and anvil are then withdrawn from the patient.

10 More particularly with respect to the structural features of the linear stapling instrument 10 of the prior art which is provided in Figure 1, the device comprises a pistol grip-styled structure 18 having an elongate shaft 19 and distal portion 20. The distal portion includes a pair of scissors-styled gripping elements 12, 14 which clamp the open ends of the colon closed. In fact only one of the two scissors-styled gripping elements, the upper jaw portion 12, moves (pivots) relative to overall structure; the other
15 remains fixed. The actuation of this scissoring means (the pivoting of the upper jaw 12 portion) is controlled by means of a grip trigger 16 maintained in the handle. A number of different means have been disclosed for holding the tips of the scissoring arms closed, including snaps, clips, collars, et al.

In addition to the scissoring means, the distal portion also includes a stapling
20 mechanism. The non-moving lower jaw 14 of the scissoring mechanism includes a staple cartridge receiving region and a mechanism for driving the staples 20 up through the clamped end of the colon, against the upper jaw portion, thereby sealing the previously opened end. The scissoring elements may be integrally formed with the shaft, or may be detachable such that various scissoring and stapling elements may be
25 interchangeable.

More particularly with respect to the structural features of the anastomosing and stapling instrument of the prior art which is provided in Figure 2, the device comprises an anvil portion 36, a staple, blade and reservoir portion 42, a shaft portion 38, and a handle portion 34. The anvil portion 36, which is selectively removable from the tip of
30 the shaft, is bullet shaped, having a blunt nosed top portion, a flat cutting support surface 48 on the bottom, and a coupling post 41 extending axially from the bottom surface.

The staple, blade, and reservoir portion 42 (SBR portion) of the instrument is provided at the distal end of the instrument, and includes a selectively advanceable and retractable coupling stem 40 for selectively receiving thereon the anvil portion. This action of the coupling stem is provided by a screw threaded shaft and worming
5 mechanism mounted in the handle 34 (described more fully below). The SBR portion is cylindrical in shape, forming a housing which has a hollow interior. It is this hollow interior which forms the reservoir 47. The blade 46 is similarly cylindrical, and seats in the inside of the housing, against the inner wall thereof. The blade is selectively advanceable axially outward from the housing, in accordance with actuation of a trigger
10 44 mechanism of the handle (again, described more fully below). On the axially outward facing surface of the cylindrical wall of the housing are a series of staple ports, through which the staples 50 of the device are discharged. The same actuation which drives the blade forward similarly drives a series of staple drivers forward within the cylindrical walls. More accurately, the staple driver is a cylindrical component which
15 has a series of protuberances on the axial end thereof, the protuberances being positioned in accordance with the distribution of staples and holes. The staples, prior to being discharged, are mounted in the holes; and they are advanced through the holes by the action of the staple driver and the protuberances thereof.

The shaft portion 38 of the instrument is a simple rigid extended structure which
20 is intended as a sheath for a pair of elongate rods. The first rod is coupled to the worming mechanism introduced above, and described more fully below with respect to the handle portion, and is the means by which the anvil portion and the coupling stem of the SBR portion are selectively advanced and retracted. The second rod is coupled to the trigger 44 of the handle at one end (also introduced above, and described more fully
25 below) and to the blade 46 and staple driver 45 at the other end. The sheath protects the patient and the instrument when it is advanced into the colon transanally. The nature of the actuation mechanisms however, requires that the shaft be rigid. This rigidity limits the length of the shaft 38; and combination, i.e. the length and rigidity of the instrument, these features limit the sections of the colon which may be treated using this device.

30 The handle 34 of this instrument of the prior art comprises a pistol grip styled structure having a turning dial 32 at the butt (i.e. the end opposing the junction of the shaft portion which the handle) and a finger actuated trigger 44. The trigger includes a

safety mechanism which physically prevents actuation unless moved out of the interference position. The turning dial 32 is actionably coupled to a worming mechanism which is used to advance the first rod of the shaft portion (thereby advancing the coupling stem and the anvil 36). The trigger functions as a basic lever to
5 push the second rod forward within the shaft, thereby advancing the blade 46 and staple driver 45.

As with many such devices of the prior art, all of these devices are considered fully disposable, and are, in fact, thrown away after a single use. They are complicated devices, having multiple moving parts, requiring substantial structural integrity and,
10 therefore, expense in manufacturing. The fact that they are used only once, and no part can be used again render the use of such devices expensive and wasteful of resources.

In addition to this failure, as can be readily observed from the preceding descriptions, the prior art devices suffer from numerous other limitations which would be desirable to overcome. These include the requirement that the surgeon manually
15 actuate a number of different functions (including those associated with the dial and trigger of the anastomosing and stapling instrument and the multiple triggers of the linear cutting and stapling instrument).

Therefore, it is a principal object of the present invention to provide an instrument for cutting, anastomosing, and stapling, for use in gastrointestinal surgery,
20 which reduces the waste of resources by permitting the reuse of portions thereof.

It is further an object of the present invention to provide an instrument assembly which reduces the requirements for the surgeon to manually actuate different components and mechanisms.

Other objects of the present invention shall be recognized in accordance with the
25 description thereof provided hereinbelow, and in the Detailed Description of Preferred Embodiments in conjunction with the remaining Figures.

Summary of the Invention

The preceding objects of the invention are provided by a carriage assembly
30 which is suitable for mounting within an electromechanical driver assembly which couples to and actuates both a linear stapling attachment and an anastomosing and stapling attachment. It may be recognized by the astute reader that both of the

instruments of the prior art, which have been described above, have similar dual actions. More particularly, the linear stapling instrument first clamps and then staples, and the anastomosing and stapling instrument advances and retracts an anvil portion, which is, in effect, a clamping action, and then drives a blade and staples forward. It is, therefore, possible to construct a single common driver assembly which can be used to actuate the functions of each, such that the differing functions may be specific only to attachments, and not to the entirety of the instrument. The present invention encompasses several components of such a driver assembly.

More particularly, the present invention comprises a plurality of motors and related components which together allow the electromechanical driver assembly to drive the flexible drive shafts of the electromechanical driver assembly and to remotely steer the distal tip of the flexible shaft portion of the electromechanical driver assembly. The present invention comprises two selectably engageable drive motors for selectably rotating drive shafts of a surgical attachment. Specifically, the drive motors each selectably rotate a drive shaft of a surgical attachment by mechanically communicating with the flexible drive shaft of the electromechanical driver assembly which ends in a coupler at the distal tip of the flexible drive shaft of the electromechanical driver assembly, to which the surgical attachment (such as one of the surgical attachments disclosed herein) may be coupled.

The present invention further comprises two selectably engageable steering motors for engaging steering wires which communicating with the flexible drive shaft of the electromechanical driver assembly. Specifically, the steering motors mechanically communicate with corresponding pulleys around which the steering wires are coiled. Selective engagement of the steering motors selectively rotates the pulleys to selectively advance or retract the steering wires. The advancement or retraction of the steering wires translates to enable the selective direction of the flexible drive shaft of the electromechanical driver assembly within a spatial plane. That is, the flexible drive shaft can be pulled in any direction, as the surgeon operator desires.

The present further comprises a pulley carriage upon which the pulleys travel within the handle of the electromechanical driver assembly, and a steering motor carriage upon which the steering motors travel within the handle of the electromechanical driver assembly. Inasmuch as the steering motors are in mechanical

communication with the pulleys as shown, the carriages travel together. The carriages travel on carriage rails which are mounted to the handle of the electromechanical driver assembly. Springs surrounding that portion of the rails between the interior wall of the electromechanical driver assembly handle and the pulley carriage bias the steering wires toward a taut state by biasing the pulley carriage away from the interior wall. In this taut state, the steering wires are able to direct the flexible drive shaft as described above. The present invention further comprises a carriage motor which mechanically communicates with the pulley carriage to selectively allow the pulley carriage to succumb to the bias of the springs or push the pulley carriage toward the interior wall of the handle of the electromechanical driver assembly with a force great enough to overcome the bias of the springs. That is, in order to permit the steering wires (and therefore the flexible drive shaft) to go limp, the surgeon operator engages the carriage motor while the surgeon operator desires the steering wires to be limp.

As stated above, the components of the present invention are suitable for mounting within an electromechanical driver assembly which couples to and actuates linear stapling attachments and an anastomosing and stapling attachment. It is anticipated that other attachments will be used as well. The electromechanical driver assembly and the mentioned attachments are described more fully hereinbelow to enable understanding of the use of the present invention.

First, with respect to the electromechanical driver, the driver has a handle (where the components of the present invention are mounted) and a flexible drive shaft. The handle has a pistol grip-styled design, having finger triggers which are independently coupled to the motors of the present invention which each perform the functions as described above. The motors are each dual-direction motors, and are coupled to manual drive switches mounted to the top of the handle, by which the user can selectively alter the turning direction of each motor. This dual-direction capacity may be most simply achieved by selecting motors which turn in a direction corresponding to the direction of current, and actuation of the drive switches alters the direction of the current accordingly. In this example, the power source supplying the motors must be a direct current source, such as a battery pack (and most desirably, a rechargeable battery pack). In the event that the electromechanical driver assembly should be useable with an alternating current, either a transformer can be included, or a more sophisticated

intermediate gearing assembly may be provided. In conjunction with the present description, the electromechanical driver assembly will be described as utilizing a rechargeable battery pack providing a direct current.

In addition to the motors and other components of the present invention, the handle further includes several other features, including a remote status indicator and at least one additional electrical supply. First, the remote status indicator may comprise an LCD (or similar read out device) by which the user may gain knowledge of the position of components (for example whether a clamping element is in the proper position prior to the driving of the staples). Second, the handle may include an additional electrical power supply and an on off switch for selectively supplying electrical power to the attachments.

Further with regard to the steering motors of the present invention, the handle also includes a manually actuatable steering means, for example, a joystick or track ball, for directing the movement of the flexible shaft (by means of the steering wires of the present invention as described above which continue into the flexible shaft portion).

In this embodiment of the electromechanical driver assembly, the driver components are integrated with the controller components. It should be noted that other embodiments of the electromechanical driver assembly may comprise a driver unit which is physically separate from a controller unit. That is, the driver unit may comprise the above-described motors and the above-described steering means, and the controller unit may comprise the above-described triggers, the above-described remote status indicator, as well as the above-described manually actuatable steering means means. The controller unit components communicate with the driver unit components by wireless transmission, for example, through infrared, radio waves, other electromagnetic waves, or ultrasound. In such a configuration, for example, the driver unit may be located out of the surgeon's arm's reach, while the controller unit may be selectively coupleable to that portion of the flexible shaft which is closer to the patient and closer to the surgeon. It should be further understood that additional embodiments of the electromechanical driver assembly may comprise more than two separate units, and such units may each house only one, or more than one, of the above-described separate components, all communicating by wireless means as described above. For example, the remote status indicator described above could be part of a third unit which

mounts to a visor wearable by the surgeon. It should be further understood that all communications between these components as described herein may in such alternative embodiments take place by wireless means.

Further with respect to the flexible shaft, the shaft comprises a tubular sheath,
5 preferably formed of a simple elastomeric material which is tissue compatible and which is sterilizable (i.e., sufficiently rugged to withstand an autoclave). Various lengths of this shaft may be provided in conjunction with the electromechanical driver assembly. In such a case, the flexible shaft and the handle portions should be separable. If separable, the interface between the proximal end of the shaft and the distal end of the
10 handle should include a coupling means for the functional components of the electromechanical driver assembly.

Specifically regarding the drive components of the shaft, within the elastomeric sheath are a pair of smaller fixed tubes which each contain a flexible drive shaft which is capable of rotating within the tube. The flexible drive shaft, itself, simply must be
15 capable of translating a torque from the drive motors of the present invention to the distal end of the shaft, while still being flexible enough to be bent, angled, curved, etc. as the surgeon deems necessary to "snake" through the colon of the patient. For example, the drive shafts may comprise a woven steel fiber cable. It shall be recognized that other drive shafts may be suitable for this purpose. In order for the distal end of the drive
20 shaft to couple with an attachment, such as the clamping and stapling device of the present invention (as described more fully below), however, the distal tips of the drive shafts must have a conformation which permits the continued translation of torque. For example, the distal tips of the drive shafts may be hexagonal, thereby fitting into a hexagonal recess in the coupling interface of the attachment. Appropriate gearing
25 mechanisms may be provided at the distal end of the shaft, or in the interfacing portion of the attachment, to ensure that the appropriate torque is provided to the attachment. As suggested above, in conjunction with the manually actuatable steering means mounted to the handle, the sheath further includes the steering wires of the present invention which are flexible, but are coupled to the inner surface of the sheath near the
30 distal end thereof. As described above, the steering wires may be axially translated relative to one another by actuation of the steering motors, which action causes the sheath to bend and curve accordingly.

Also as suggested above, in conjunction with the LCD indicator of the handle, the shaft further contains an electrical lead for coupling to the attachments. This electrical lead channels a signal from the attachment to the handle for indicating the status of the attachment (for example, whether a clamping function is holding).

5 Similarly, a second electrical lead may be provided to supply power to separate aspects of the attachment if so required (for example, as will be described more fully with respect to one embodiment of the linear stapling attachment, the use of a selectively engageable electromagnetic seal for ensuring continued clamping through the stapling process may be provided and require power selectively provided from the handle's
10 power supply.

More particularly, with respect to the linear clamping and stapling attachment, which has several different potential embodiments, two of which are disclosed herein as examples, the attachment is fitted with two drive extensions, which in operation function as extensions of the flexible drive shafts of the electromechanical driver
15 assembly. That is, when the attachment is mated to the electromechanical driver assembly, the drive extensions are in mechanical communication with the flexible drive shafts such that the activation of the drive shaft motors activates the drive extensions within the linear clamping and stapling attachment. In each embodiment of the attachment, the first drive extension enables a linear clamping mechanism, while the
20 second drive extension enables a stapling mechanism. In one embodiment, the linear clamping mechanism comprises a scissors-cuff system whereby the pivoting upper jaw of the scissors is clamped to the fixed lower jaw of the scissors as a cuff enclosing a length of the scissors is moved from the hinged end of the scissors toward the closing end of the scissors. The scissors can be unclamped as the cuff is returned to its original
25 position. In this embodiment, the first drive extension moves the cuff forward or backward, depending on the turning direction of the corresponding motor in the electromechanical driver.

In a second embodiment, the linear clamping mechanism comprises a separating jaw system whereby an upper jaw is raised and subsequently lowered to meet a lower
30 jaw to effect a clamping. In this embodiment, the first drive extension engages a pair of threaded vertical shafts which raise or lower the upper jaw depending on the turning direction of the corresponding motor in the electromechanical driver assembly.

In each of these embodiments, the stapling mechanism comprises a replaceable tray of open staples set within the lower jaw and a set of corresponding staple guides fitted on the upper jaw, such that when the linear clamping mechanism is in a closed position, the open staples immediately oppose the corresponding staple guides. The stapling mechanism further comprises a wedge pushing system whereby once the linear clamping mechanism is in a closed position, a wedge riding in a channel below the tray of open staples is pushed through the channel. As the wedge moves through the channel, a sloping surface of the wedge pushes the open staples against the corresponding staple guides, thereby closing the staples. After the staples have been closed, the wedge is pulled back through the channel. The second drive extension pushes or pulls the wedge through the channel, depending on the turning direction of the corresponding motor in the electromechanical driver, by engaging a threaded horizontal shaft upon which the wedge, having a matching inner thread, rides.

The distal ends of the scissoring or linearly closing jaws may further include an electromagnetic securing mechanism which serves to hold the distal tips of the jaws together during the stapling step. This is preferred insofar as the action of driving the staples upwardly against the staple guides of the upper jaw may serve to open the jaws. In addition, the electromagnetic securing mechanism may be coupled in electrical communication with the LCD indicator mechanism in the handle (described above) such that the surgeon operating the device may be made aware of when the jaws have closed and the device is in a safe staple-driving position.

Referring now to the anastomosing and stapling attachment, a preferred embodiment is described hereinbelow as a single example of the different variations which could be constructed for the equivalent purpose. As with the linear stapling attachments described above, however, this example demonstrates the universal applicability of the overall electromechanical driver assembly mechanism. This attachment comprises an anvil portion, and a staple, blade and reservoir portion, which includes a pair of turning drive shafts which are coupleable to the drive components of the shaft element described above, and a corresponding pair of advancing and retracting nuts mounted to the turning drive shafts, but which are prevented from rotating and therefore linearly advance and retract along the shafts when they turn.

The anvil portion includes is bullet shaped, having a blunt nosed top portion, a flat cutting support surface on the bottom, and a freely rotating coupling post extending axially from the bottom surface. This coupling post is designed to be selectively coupleable and removable from the corresponding nut mounted to one of the turning
5 drive shafts.

The staple, blade, and reservoir portion (SBR portion) is cylindrical in shape, forming a housing which has a hollow interior. It is this hollow interior which forms the reservoir. On the axially outward facing surface of the cylindrical wall of the housing are a series of staple ports, through which the staples of the device are discharged. A series
10 of staple drivers are mounted within the cylindrical walls, beneath the staple ports, for driving the staples therethrough. More accurately, the staple drivers are a series of protuberances on the outer edge of a single cylindrical component which seats in the wall of the SBR portion. The staples, prior to being discharged, are mounted in the holes; and they are advanced through the holes by the forward motion of the staple
15 driver and the protuberances thereof. The blade is similarly cylindrical, and seats in the inside of the housing, against the inner surface of the wall thereof. Both the blade and the staple driver are mounted to the second nut, which is, in turn, mounted to the other turning drive shaft. As the tuning drive shaft rotates, the nut (which is constrained against rotating) advances along the shaft, thus linearly advancing the blade and staple
20 driver. The blade and the staple driver are, therefore, selectively advanceable axially outward from the housing, in accordance with actuation of the appropriate trigger on the handle.

In a preferred embodiment, the anvil portion and the SBR portion further comprise an electromagnetic sensor mechanism, coupled to the LCD indicator of the
25 handle, which sensor is activated when the two portions have approached each other to the extent necessary for a safe staple firing, whereby the surgeon may have remote knowledge of the state of the attachment disposed within the colon.

In practice, this attachment is utilized, once the section of the colon which is to be removed has been resected (but prior to the linear clamping and stapling step is
30 complete), in the following manner. The surgeon begins by coupling the anastomosing and stapling attachment to the electromechanical driver assembly and advancing the anvil portion to its fullest extent. The anvil head is then removed and inserted into the

partially opened proximal end. As described above, this proximal end is then sutured closed. The surgeon then advances the shaft and the SBR portion of the attachment up the colon until it extends through the stapled distal end of the colon. The surgeon then couples the anvil to the advancing and retracting nut of the corresponding drive shaft.

- 5 Subsequent triggering of the motor in the handle causes the anvil to retract toward the SBR portion. As stated above, in a preferred embodiment, the base of the anvil and the outer edge of the SBR housing comprise an electromagnetic sensor which is coupled to the LCD indicator of the handle, thereby permitting the surgeon to know when the anvil and the SBR have come close enough to drive the blade and staples. Subsequent
- 10 actuation of the other trigger on the handle causes the corresponding other turning drive shaft to advance the blade and staple driver into contact with the opposing face of the anvil. The blade cuts through the stapled-closed ends of the colon, leaving the tissue which has been severed in the interior reservoir. Simultaneous with the cutting, the freshly opened ends are joined together by the series of staples which are advanced
- 15 through holes in the perimeter edge of the SBR (being pressed against and closed by the opposing face of the anvil). The attachment and the flexible shaft are then withdrawn from the patient.

- It should be evident that the present invention provides a necessary component to the electromechanical driver assembly for the purposes of overcoming the limitations
- 20 of the prior art. Specifically, the present invention enhances the ability of the electromechanical driver assembly to be reused, by providing in a compact form all of the components necessary to perform the functions of the electromechanical driver assembly and the associated attachments. Therefore, the present invention helps to provide an instrument for cutting, anastomosing, and stapling, for use in
- 25 gastrointestinal surgery, which reduces the waste of resources by permitting the reuse of portions thereof. Further, the electromechanical basis of the components of the present invention reduces the requirements for the surgeon to manually actuate different components and mechanisms. That is, through the automation and power-driver functions of the present invention, the surgeon endures less fatigue and enjoys greater
- 30 accuracy throughout the surgery.

A Brief Description of the Drawings

Figure 1 is a side perspective view of a linear clamping and stapling instrument of the prior art;

Figure 2 is a side perspective view of an anastomosing and stapling instrument of the prior art;

Figure 2a is a cut-away perspective view of a carriage assembly of the present invention;

Figure 3 is a side view of a handle and flexible shaft of an electromechanical driver assembly, wherein certain features of the present invention are shown in phantom;

Figure 4 is a side view of one embodiment of the linear clamping and stapling attachment for use with the electromechanical driver assembly, wherein internal features of the elements are provided in phantom;

Figure 5 is a side view of a second embodiment of the linear clamping and stapling attachment for use with the electromechanical driver assembly, wherein internal features of the elements are provided in phantom; and

Figure 6 is a side cut-away view of an anastomosing and stapling attachment for use with the electromechanical driver assembly.

A Detailed Description of the Preferred Embodiments

While the present invention will be described more fully hereinafter with reference to the accompanying drawings, in which particular embodiments are shown, it is to be understood at the outset that persons skilled in the art may modify the invention herein described while achieving the functions and results of this invention.

Accordingly, the descriptions which follow are to be understood as illustrative and exemplary of specific structures, aspects and features within the broad scope of the present invention and not as limiting of such broad scope. Like numbers refer to similar features of like elements throughout.

More particularly, the present invention, a carriage assembly for controlling a steering wire steering mechanism within a flexible shaft, is in the preferred embodiment suited for use with an electromechanical driver assembly and suitable attachments such as the linear clamping and stapling attachment and the anastomosing and stapling

attachment disclosed herein. The interrelation of these components should be clear from the above description and the discussion below.

Referring now to Figure 2a, the present invention comprises a plurality of motors. It is to be understood that any or all of the motors are selectably engageable by the surgeon operator via selection buttons or the like on the exterior surface of the handle of the electromechanical driver assembly, and are connected to the power source or power sources (not shown) of the electromechanical driver assembly. The power source is preferably, but is not required to be, a removable and rechargeable direct current battery source. It shall be understood that alternative power sources, including dual direct current sources or single remote alternating current sources (such as the alternating current provided from standard United States 120 Volt, 60 Hertz wall outlets) may be used in conjunction with alternative embodiments. In the event that the electromechanical driver assembly should be useable with an alternating current, either a transformer can be included between the motors of the present invention and the power source, or a more sophisticated intermediate gearing assembly may be provided between the motors of the present invention and any extended turning drive shafts.

The carriage assembly comprises two selectably engageable drive motors 100 for selectably rotating drive shafts of a surgical attachment (not shown). Specifically, the drive motors 100 each selectably rotate a drive shaft of a surgical attachment by mechanically communicating with a drive shaft 120 which mechanically couples to the flexible drive shaft (shown on Figure 3) of the electromechanical driver assembly which ends in a coupler (shown on Figure 3) at the distal tip of the flexible drive shaft of the electromechanical driver assembly, to which the surgical attachment (such as one of the surgical attachments disclosed herein) may be coupled.

The carriage assembly further comprises two selectably engageable steering motors 130 for engaging steering wires 140 communicating with a flexible shaft of an electromechanical driver assembly (shown on Figure 3). Specifically, the steering motors 130 mechanically communicate via steering shafts 150 connected by torque-translating joints (not visible) to corresponding pulleys 160 around which the steering wires 140 are coiled as shown. Selective engagement of the steering motors 130 selectively rotate the steering shafts 150 which selectively rotate the pulleys 160 to selectively advance or retract the steering wires 140. For example, when the pulley 160

as shown is rotated toward the steering motor 130, the upper portion 170 of the steering wire 140 is pulled toward the steering motor 130 and the lower portion 180 of the steering wire 140 is pulled away from the steering motor 130. This engagement translates to enable the selective direction of the flexible shaft of the electromechanical driver assembly within a spatial plane. That is, for example, the pulling of the upper portion 170 as described pulls the flexible shaft of the electromechanical driver assembly upward, while the pulling of the lower portion 180 as described pulls the flexible shaft downward. It is to be appreciated further in this example that when the other pulley 160 is rotated, the flexible shaft is pulled to the left or right, as the surgeon operator desires.

The carriage assembly further comprises a pulley carriage 190 upon which the pulleys 160 travel within the handle of the electromechanical driver assembly, and a steering motor carriage 200 upon which the steering motors 130 travel within the handle of the electromechanical driver assembly. To be clear, inasmuch as the steering motors 130 are in mechanical communication with the pulleys 160 as shown, the carriages 190, 200 travel together. The carriages 190, 200 travel on carriage rails 210 which are mounted to the handle of the electromechanical driver assembly. Springs 220 surrounding the rails 210 as shown bias the steering wires 140 toward a taut state by biasing the pulley carriage 190 away from the interior wall of the handle of the electromechanical driver assembly. In this taut state, the steering wires 140 are able to direct the flexible shaft of the electromechanical driver assembly as described above. The carriage assembly further comprises a carriage motor 240 which mechanically communicates with the pulley carriage 190 to selectively allow the pulley carriage 190 to succumb to the bias of the springs 220 or push the pulley carriage 190 toward the interior wall of the handle of the electromechanical driver assembly with a force great enough to overcome the bias of the springs 220. That is, in order to permit the steering wires 140 (and therefore the flexible shaft) to go limp, the surgeon operator engages the carriage motor 240 while the surgeon operator desires the steering wires 140 to be limp.

The carriage assembly described above is preferably fixed within an electromechanical driver assembly. Referring now to Figure 3, with respect to the electromechanical driver assembly 100, the electromechanical driver assembly has a handle portion 102 and a flexible drive shaft portion 104. The handle 102 includes a

portion which is shaped in a manner which is easily gripped by the surgeon operator, for example, in the embodiment provided herein the handle comprises a pistol grip-styled portion 106. The grip portion 106 includes at least two, and in the embodiment shown exactly two, independently finger actuable triggers 108a,108b. The finger
5 triggers 108a,108b are independently coupled to the drive motors of the present invention (see items 100 on Figure 2a as described above) shown here as items 110 and 112, housed within the interior volume of the handle 100. As described above and shown here, each drive motor 110, 112 (items 100 on Figure 2a) turns a separate flexible drive shaft (described more fully hereinbelow).

10 Although not shown on Figure 3, the other components of the carriage assembly of the present invention are also fixed within the handle portion of the electromechanical driver assembly, including the steering motors and carriage motor. The drive motors and these additional motors are dual-direction motors, and all are coupled to finger actuable switches similar to the finger actuable triggers 108a, 108b shown on Figure
15 3. The motors are also each separately coupled to the power source 114 (which is a common source in the shown embodiment) and manual switches similar to the manual drive switch 116 shown on Figure 3. The manual drive switch 116 is provided on the top of the handle 100, such that the surgeon operator can selectively alter the turning direction of each drive motor. Additional manual switches can similarly be used by the
20 surgeon operation to selectively alter the turning direction of the other motors. In the shown embodiment, the power source 114 supplying the motors is a single removable and rechargeable battery pack supplying direct current. It shall be understood that alternative power sources, including dual-direction current sources or single remote alternating current sources (such as the alternating current provided from standard
25 United States 120 Volt, 60 Hertz wall outlets) may be used in conjunction with alternative embodiments. In the event that the electromechanical driver assembly should be useable with an alternating current, either a transformer can be included between the motors and the power source, or a more sophisticated intermediate gearing assembly may be provided between the motors and the extended turning drive shaft.

30 Further with regard to Figure 3, in addition to the motors and other components of the carriage assembly and the related power and switch elements, the handle 100 further includes a remote status indicator 118 and associated electrical circuit 120. The

indicator means in this embodiment comprises an LCD mounted to the upper portion of the handle. It shall be understood that an equivalent function may be achieved by mounting an audible alarm, or other plain sensory stimulation mechanism, on the handle. The remote status indicator 118 is coupled to an associated electrical circuit
5 which extends along the handle and the flexible shaft and couples to a corresponding electric circuit in the selected surgical attachment (see Figures 4-6). The disposition of the surgical attachment, for example in a closed or open position, is associated with the circuit in the surgical attachment being in an open circuit or closed circuit state. The closed circuit state causes the remote status indicator LCD to light up, whereas the open
10 circuit state causes the LCD to go out.

Specifically with further regard to the steering motors, pulleys, steering wires and associated components of the present invention, the handle also includes a manually actuatable steering means, which in the present embodiment comprises a trackball 124 which actuates the steering motors of the present invention as described
15 above, which actuates the steering wires 126 (items 140 on Figure 2a). The steering wires extend along the flexible shaft portion 122 (described more fully hereinbelow) and are coupled to the tip of the flexible shaft 122. When the trackball 124 is rotated, the steering wires 126 are pulled by the steering motors of the present invention, and the tip of the flexible shaft 122 turns correspondingly.

20 More particularly, with respect to the flexible shaft 122, the shaft comprises a tubular sheath 128 which is formed of a simple, tissue compatible, elastomeric material. As this device is to be reused, it is important that the material be sterilizable (i.e., sufficiently rugged to withstand an autoclave). While the embodiment shown comprises a contiguous handle 100 and shaft 122, it shall be understood that one having
25 ordinary skill in the art may provide an alternative embodiment having a separable handle and shaft, thus permitting alternative shaft lengths for alternative purposes. In such cases, the flexible shaft 122 and the handle 100 portions should include an interface between the proximal end of the shaft and the distal end of the handle which should include a coupling means for the electromechanical components.

30 Specifically regarding the drive components 130a, 130b of the shaft 122, within the elastomeric sheath 128 are a pair of smaller fixed tubes 134a, 134b which each contain a flexible drive shaft 136a, 136b which is capable of rotating within the

corresponding tube 134a, 134b. Each flexible drive shaft 136a, 136b itself simply must be capable of translating a torque from the drive motors of the present invention in the handle of the electromechanical driver assembly to the distal end 138a, 138b of the shaft 122, while still being flexible enough to be bent, angled, curved, etc. as the surgeon
5 deems necessary to "snake" through the colon of the patient. For example, the flexible drive shafts may comprise a woven steel fiber cable, a high tensile strength polymeric material, or a sufficiently flexible unitary metal shaft.

In order for the distal ends 138a, 138b of the flexible drive shafts 136a, 136b to couple with an attachment, such as the linear clamping and stapling attachment (see
10 Figures 4 and 5), the distal tips 138a, 138b of the flexible drive shafts 136a, 136b must have a conformation which permits the continued translation of torque. In the shown embodiment, this coupling is achieved by a geometric fitting. More precisely, the distal tips of the flexible drive shafts are hexagonal, and thereby fit into hexagonal recesses in the coupling interface of the attachment. In certain embodiments of the
15 electromechanical driver assembly, the attachment and the distal end of the flexible drive shaft should include a collar, or other aligning means, for facilitating the fitting of the attachment onto the distal end of the flexible drive shaft. Additionally, the tip of the flexible drive shaft may include the distal ends of the circuit 120 which is coupled to the LCD 118, as well as other coupling components necessary to translate the functionality
20 of the electromechanical driver assembly to the attachments.

Referring now to Figures 4 and 5, two alternative linear clamping and stapling attachments are shown. The first linear clamping mechanism, shown in Figure 4, comprises a separating jaw system comprising a lower jaw 150 and an upper jaw 152 and a proximal interfacing end member 154. This proximal end member 154 includes
25 two hexagonal shaped sockets 156a, 156b into which the distal tips 138a, 138b of the drive shafts of the electromechanical driver assembly couple. Each of the sockets is formed in the end of a corresponding horizontal turning shaft 158a, 158b. The upper horizontal turning shaft 158a is coupled, by means of a transverse gearing member, to a threaded vertical shaft 160 which extends through a correspondingly threaded bore 162
30 of the upper jaw 152. The upper jaw 152 has a linear track coupling means 166 which corresponds and couples to a linear track 168 formed in the side of the interface end member 154 which is opposite the driver coupling sockets 156a, 156b. Subsequent

turning of the upper horizontal turning shaft 158a causes the vertical turning shaft 160 to turn. As this shaft 160 turns, the upper jaw 152 rides up and down within the track of the end member 154.

The lower horizontal turning shaft 158b extends axially through the lower jaw 150, which, in turn is fixed to the proximal end member 154. Mounted around this axially extending shaft 158b is a wedge driver mechanism 166 which includes a threaded bore. This threaded member 166 is locked within a track 167, which prevents the member 166 from rotating when the shaft 158b turns. Rather, the wedge member 166 rides linearly along the track 167 and along the threading of the shaft 158b. Mounted within a recess 168 in the face of the lower jaw 150 which opposes the upper jaw 152, directly above the wedge member 166 is a replaceable tray of staples. The wedge driver has a sloped frontal surface 172 which contacts the staple 174 and causes it to be driven upwardly out of the tray 170. When the upper jaw 152 is in close proximity to the lower jaw 150, the staples are closed when they contact the opposing face of the upper jaw 152 (by the action of staple closing guide recesses 176 formed therein).

At the distal tip of the upper and lower jaws are two opposing magnetic sensors 178a, 178b, each coupled to a circuit component which mates with the distal ends of the LCD indicator 118 circuit 120. When the jaws come together, the circuit is closed and the LCD indicator is lighted, indicating that the staples may be safely fired.

In operation, the surgeon cuts the tube of the colon on either side of the cancerous tissue, thereby creating two ends of the bowel. The surgeon uses the linear clamping and stapling attachment to temporarily staple the exposed ends. More particularly, the linear clamping and stapling attachment is mated to the distal end of the electromechanical driver assembly. By manually actuating one trigger (the one which causes the rotation of the upper shaft 136a) the upper jaw 152 opens relative to the lower jaw 150. The open end of the colon is then placed between the jaws 150, 152 and the jaws are closed by switching the drive direction for the upper shaft 136a and driving the upper jaw in the opposite direction. The jaws are thereby shut on the end of the colon. At this time the LCD indicator 118 in the handle should light up, indicating that the staples may be safely advanced.

Triggering the second shaft 136b into rotation causes the wedge driver 166 to slide along the track 167 in the lower jaw 150. This drives the staples 174 through the

end of the colon and closes them against the staple closing guide recesses 176. The jaws are then reopened and the wedge driver 166 is retracted within the lower jaw 150, the tray 170 of staples 174 is replaced, and the process is repeated for the other open end of the colon.

5 Referring now Figure 5, the second embodiment 180 of the linear clamping and stapling attachment of the present invention is described. In the present embodiment the coupling interface 154 is largely equivalent to the first embodiment inasmuch as the hexagonal ends of the shaft portion are inserted into the corresponding socket ends 156a,156b of the attachment. As before, the shafts of the electromechanical driver
10 assembly turn rotating members within the attachment. In this embodiment however, both turning members 158a,158b are horizontal. Mounted to the shaft interfacing member is a fixed lower jaw 150 and a moving upper jaw 152. In this embodiment, the upper jaw 152 is mounted to the lower jaw 150 by means of a spring loaded pivot, which biases the upper jaw into an open disposition relative to the lower jaw. Mounted to the
15 upper turning shaft however, is a linearly tracked cuff 187 which seats around the upper and lower jaw, the advancement of which causes the jaws to come together. The lower jaw includes exactly the same staple 174 tray recess and linearly driven threaded wedge staple pushing mechanism 166. Also, the electromagnetic sensor and circuit of the first embodiment is included to indicate to the surgeon when the section of colon has been
20 fully clamped and the staples should be driven.

More particularly, after the surgeon has resected the diseased portion of the colon, the end of the colon is placed between the jaws of the attachment. By actuating the first trigger (and driving the upper shaft), the cuff member 187 advances axially along the outside of the upper and lower jaws 150,152, thus closing the upper jaw onto
25 the colon and lower jaw. Once fully closed, the electromagnetic sensor circuit indicates to the surgeon operator that the staples may be fired, and correspondingly, actuation of the second trigger causes the wedge driver to advance and drive the staples through the colon section. Reverse biasing the motor for the upper turning shaft causes the cuff to retract and the upper jaw to open, thus releasing the now sealed colon end.

30 With reference now to Figure 6, a preferred embodiment of the anastomosing and stapling attachment 200 is described. This attachment comprises an anvil portion 202, and a staple, blade and reservoir (SBR) portion 204, which includes a pair of turning

drive shafts 206a,206b which are coupleable to the drive components 136a,136b of the electromechanical driver assembly described above with reference to Figure 3, and a corresponding pair of advancing and retracting members 208a,208b mounted within tracks and to the turning drive shafts, which are thereby prevented from rotating and therefore linearly advance and retract along the shafts 206a,206b when they turn. More particularly, the base of the SBR portion 204 includes a coupling interface 203 which includes a pair of hexagonal recesses 205a,205b formed in the bases of the threaded turning shafts 206a,206b.

The anvil portion 202 is bullet shaped, having a blunt nosed top portion 210, a flat cutting support surface 212 on the bottom, and a coupling post 214 extending axially from the bottom surface. This coupling post 214 mounts to the first advancing and retracting member 208a which is mounted within a linear track whereby rotation of the shaft 206a causes the member 208a and the anvil 202 coupled thereto to move axially, but not rotationally.

The staple, blade, and reservoir portion (SBR) portion 204 is cylindrical in shape, forming a housing which has a hollow interior 216. It is this hollow interior which forms the reservoir. On the axially outward facing surface 218 of the cylindrical wall 220 of the housing are a series of staple ports, through which the staples 224 of the device are discharged. A unitary blade and cylindrical staple driver component 226 is seated within the housing. More particularly, the blade and staple driver component comprises a single element having two concentric cylindrical portions. The blade portion 228 seats within the hollow interior 216, against the interior wall 230 thereof. The staple driver portion 232 seats within the wall 230 of the SBR portion and includes a series of outwardly projecting protuberances which push against staples mounted within the staple ports.

The blade 228 and staple driver portions 232 are coupled at the interior end thereof to a threaded member 208b which seats around turning shaft 206b. The threaded member 208b is constrained within a linear track so that the blade and staple driver are advanced linearly upon rotation of the turning shaft 206b.

In addition, the anvil 202 and the SBR 204 portions each comprise corresponding electromagnetic sensor circuit components 240a,240b which couple to the LCD indicator 118 in the handle.